4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0433] (formerly Docket No. 2007D-0169)

Draft Guidance for Industry on Bioequivalence Recommendation for Lenalidomide Capsules; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Draft Guidance on Lenalidomide." The guidance provides specific recommendations on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for lenalidomide capsules. The draft guidance is a revised version of a previously published draft guidance on the subject.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on the draft guidance before it begins work on the final versions of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, "Bioequivalence Recommendations for Specific Products," which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm. As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for lenalidomide capsules.

Revlimid (lenalidomide capsules), approved by FDA on December 27, 2005, is a thalidomide analogue indicated for the treatment of: Multiple myeloma, in combination with dexamethasone, in patients who have received at least one prior therapy and also in patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities. Revlimid is designated as the reference listed drug, and therefore any ANDAs for generic lenalidomide capsules must demonstrate BE to the Revlimid prior to approval. There are no approved ANDAs for this product.

In June 2010, FDA posted on its Web site a draft guidance for industry on the Agency's recommendations for BE studies to support ANDAs for lenalidomide capsules. In that draft guidance, FDA recommended studies in the 15 milligram (mg) and 25 mg strengths of lenalidomide capsules to demonstrate BE. FDA has now determined that a BE study in the 15 mg strength is unnecessary and is revising the guidance to remove that recommendation. FDA also is revising the guidance to recommend that a request for a waiver of in vivo testing be submitted for the 2.5 mg, 5 mg, 10 mg, and 15 mg strengths based on: (1) Acceptable fasting and fed bioequivalence studies on the 25 mg strength, (2) proportional similarity of the formulations across all strengths, and (3) acceptable in vitro dissolution testing of all strengths.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for lenalidomide capsules. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov.. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Electronic Access

Persons with access to the Internet may obtain the documents at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: October 31, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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